REMARKS

Applicant has amended claims 26-31. Support for the new claims is found in the original claims, and Figures 1 through 4.

Drawings

The drawings are objected to for failing to comply with 37 CFR § 1.84(p)(5) because they do not include references to all those mentioned in the description. As set forth in 37 CFR § 1.121(d), "Any changes to an application drawing ... must be submitted on a replacement sheet of drawings which shall be an attachment to the amendment document, and, in the top margin labeled "Replacement Sheet. ... A marked-up copy of any amended drawing figure, including annotations indicating changes made, may be included. The marked-up copy must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change to the drawings." Thus, Applicant submits herewith a Replacement Sheet for Figures 2a through 2f, as well as a marked-up copy of Figures 2a through 2f indicating changes made, in red. The changes add all of the reference numbers referred to in the application, but not originally present on any of Figures 2a through 2f. Applicant respectfully requests approval for these changes, and submits that the amendments do not constitute new matter, they merely bring the figures in line with the description in the text of the specification.

Amendments to the Specification

Because of inconsistencies with the description of the drawings in Figs. 2a through 2f, relative to the missing references numbers, Applicant has amended the specification to be consistent with the proposed changes to the drawings. Basically, aperture/measuring chamber (19) has been amended to be aperture/measuring chamber (12), as cited elsewhere in the text, and in Figure 1. Applicant respectfully submits that these amendments do not constitute new matter, and merely reflect corrections made to the description that are consistent with the drawings.

Amendments to the Claims

Claims 26 and 30 are amended to more clearly recite the features of the claimed medicament delivery system. Support for the amendments is found in the original claims, specification, and figures, particularly p. 9 and Figures 2a through 2f.

35 U.S.C. §§ 102(e) Rejections

Amended claims 26 and 30 specify that the metering member comprises two components: a medicament dispensing member and a medicament measuring member. The two components cooperate so that the metering member can move from a first position, in which medicament is transferred from the reservoir to the measuring chamber, to a second position, in which medicament is transferred from the measuring chamber to the dispensing cup, and to a third position in which medicament is delivered to the medicament delivery position.

These features are not disclosed in US6,119,688 (Whaley). In particular, Whaley does not disclose a metering member comprising two cooperating components, such that medicament is transferred first from a reservoir to a measuring member, then from the measuring member to a dispensing cup, the medicament in the dispensing cup then being presented to a medicament delivery position. Instead, Whaley (see Figs 3-5) simply has a rotating "dosage member 30" with a "dosage chamber 32". Medicament is loaded into the dosage chamber 32 and that chamber is brought, by rotation of the dosage member 30, into alignment with a "pressure outlet 23", from which position the dose of medicament is dispensed (see col. 8, lines 34-41, and col. 12, lines 42-29, Whaley).

Furthermore, Whaley does not disclose a dispensing cup provided with an air duct to allow air to be sucked through the metering member upon inhalation by a patient, as required in amended claims 26 and 30. Instead, Whaley discloses a dosage chamber (32) that is brought into registration with a pressure outlet passageway (23), during use, while a patient is inhaling air through a separate air entrance passageway (19). In this operative configuration, pressurized fluid passes through the pressure outlet passageway so as to discharge the medicament within the dosing chamber into the air stream being inhaled by a patient through the air entrance passageway. Neither the dosing chamber nor the pressure outlet passageway constitutes a dispensing cup, and air is not sucked through the

metering member upon inhalation by a patient, but is instead caused to flow by a pressurization assembly of the device, as described at col. 10, lines 51-19, or Whaley. For the above reasons, Applicant respectfully submits that amended claims 26 and 30 are novel over Whaley.

Moreover, the amended claims are also non-obvious in light of Whaley. The measuring chamber of the invention, as defined by amended claims 26 and 30 is able, in the first position, to receive a measured dose of medicament and then, at the second position, to transfer the measured dose to the dispensing cup. Finally, a third position, the patient is able to draw air through the duct of the metering member so that the measured dose of medicament is discharged into the inhalation passage and inhaled.

The provision of a measuring chamber that transfers medicament from the reservoir to the dispensing cup enables the dispensing cup to be formed with an air duct without any loss of accuracy in the measured dose. The air duct increases the airflow through the dispensing cup, and hence facilitates discharge of the medicament into the inhalation passage and delivery of the medicament to the patient.

The invention as defined by amended claims 26 and 30 therefor enables improved medicament delivery devices and inhalers to be formed that are more efficient at delivering medicaments to a patient for a given airflow through the device. This is particularly important for breath-actuated inhalers that have no additional pressure source from promoting airflow.

In contrast, Whaley discloses an inhaler comprising means for introducing dry powder medicament into a dosage chamber in a packed, agglomerated form (see col. 2, lines 5-10), and a pressurization assembly for discharging the dose from the dosage chamber (see col. 2, lines 48-50) such that the dose can be inhaled by a patient.

Furthermore, in the presently claimed invention, the fact that medicament is transferred from the reservoir to the dispensing cup via an intermediate component (measuring member) means that the dispensing cup is not directly exposed to the interior of the reservoir at any time. This means that ingress of moisture, eg moisture from the patient's breath that may condense in the dispensing cup into the reservoir, is inhibited. As described in the passage bridging pages 3 and 4 of the present application, the

reservoir is sealed by the measuring member, before transfer of medicament from the measuring member to the dispensing cup takes place.

Applicant respectfully submits that a skilled person attempting to devise a medicament delivery device or inhaler having improved efficiency at delivering medicament to a patient for a given airflow through the device, without any loss of dose accuracy, and/or seeking to devise a medicament delivery device or inhaler in which ingress of moisture to the medicament reservoir is inhibited, would not look to Whaley for guidance. This is because Whaley is concerned with improving the accuracy of dose by introducing dry powder medicament into a dosage chamber in a packed, agglomerated form, and then utilizing a pressurized air source to discharge the dose for inhalation. Whaley is not therefore concerned with improving efficiency at delivering medicament to a patient for a given airflow through the device. Therefore, there is no suggestion or motivation to modify Whaley to arrive at the presently claimed invention.

And even if a skilled person were to turn to Whaley for guidance, Applicant respectfully submits that Whaley does not provide any teaching towards the invention, as required in amended claims 26 and 30. Indeed, Whaley teaches away from the invention of amended claims 26 and 30.

In particular, Whaley discloses an inhaler comprising means for introducing dry powder medicament into a dosage chamber in a packed, agglomerated form (see col. 2, lines 5-10). This feature would reduce the efficiency of a device at delivering medicament to a patient for a given airflow through the device. The user of a device as described by Whaley does not simply suck the medicament out of the dosage chamber; rather, Whaley relies on a source of pressurized fluid to expel the medicament into the airflow (and presumably at the same time to deagglomerate the packed, agglomerated medicament into a form suitable for inhalation).

Furthermore, the cross-section of the pressurized outlet passageway of Whaley is preferably slightly larger than that of the dosage chamber so as to afford complete expulsion of the medicament from the dosage chamber (see col. 7, lines 55-58). Whaley therefore teaches away from a device in which medicament is transferred from a measuring chamber to a dispensing cup having an air inlet, because the air inlet of such a

device would necessarily be of smaller cross-sectional dimensions relative to the dispensing cup.

Given that Whaley does not disclose the advantage of first transferring the medicament to the measuring chamber and then subsequently to the dispensing cup - all the while providing an accurately delivered dosage of the medicament to a patient for a given airflow, in the absence of pressurized fluid - and that Whaley does not suggest modifying the disclosed delivery device/system to that of the presently claimed invention, as detailed above, Applicant respectfully submits that the currently pending claims 26-31 are novel over Whaley and also non-obvious in light of Whaley. Reconsideration and withdrawal of the 102(2) anticipation rejections is therefore requested.

Submission of a Supplemental IDS

The supplemental IDS submitted with Response A, filed July 6, 2004 is being re-submitted with this response and Request for Continued Examination. Applicant respectfully requests consideration of the references.

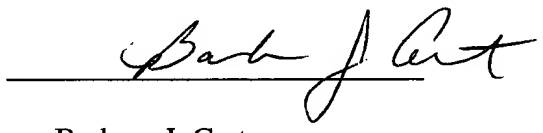
CONCLUSION

It is believed that all pending claims are in condition for allowance and so reconsideration of the claims and a notice of allowance are therefore requested.

Applicant hereby petitions for a two-month extension of time and that all fees for the extension, Request for Continued Examination, and submission of the supplemental IDS (if required) be charged to deposit account number 19-4972. In the event that an additional extension of time is required, Applicant submits this petition for an additional extension of time. Applicant also requests that any such fees be charged to deposit account number 19-4972, as well as any additional fees that may be required for the timely consideration of this application. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Date: June 23, 2005

Respectfully submitted,



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ANNOTATED SHEET

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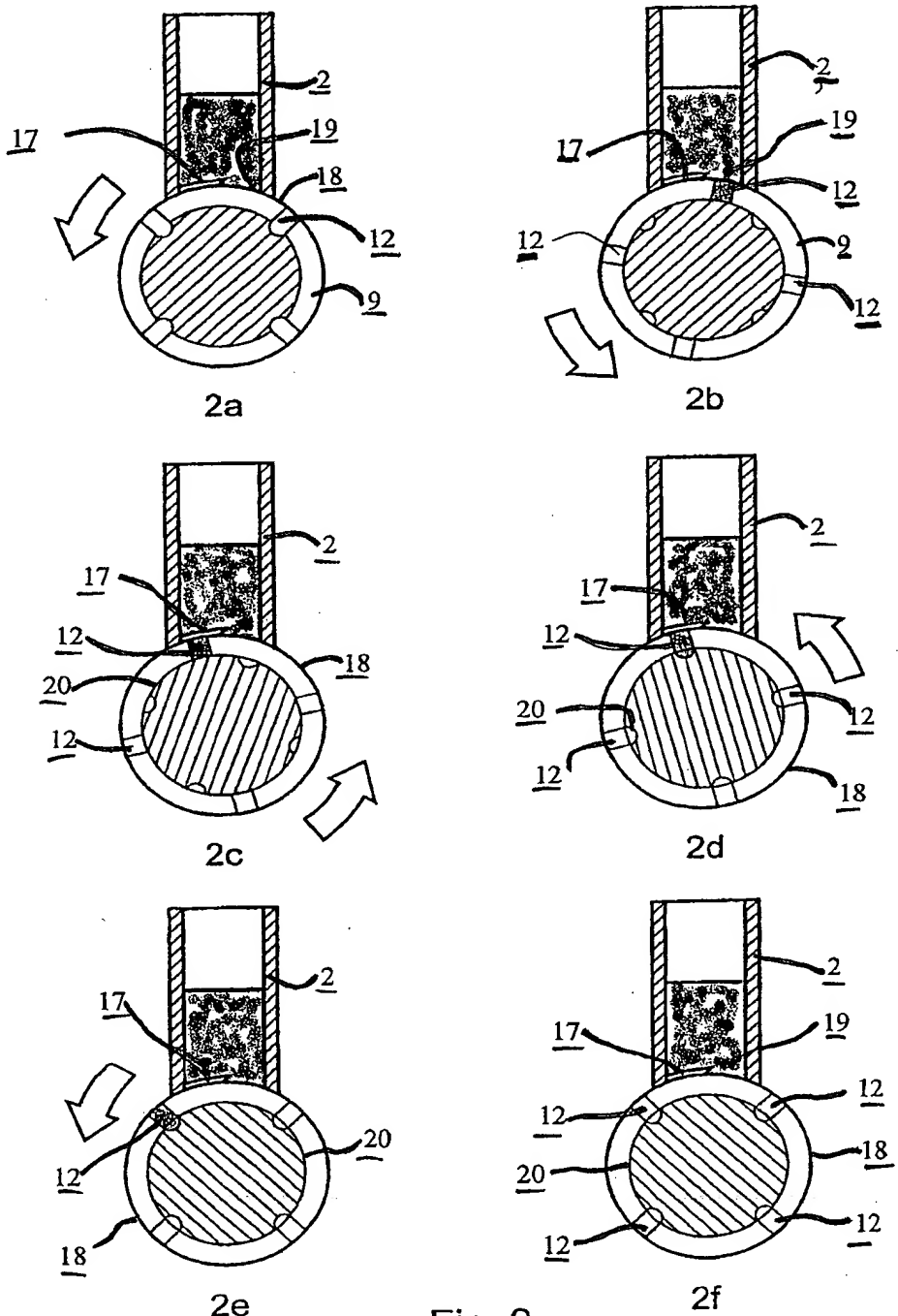

Fig. 2